those current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.

PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 29, Tess Dernbach, and Speaker 30, Mary Angly. If you come to the speakers' table. Is Mary Angly in the room? Okay, we'll come back to her at the end.

MS. DERNBACH: My name is Tess Dernbach, T-E-S-S,

D-E-R-N-B-A-C-H. I am a third-year law student at Columbia Law School and a legal intern at Earthjustice, speaking on behalf of Earthjustice. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," requires a choice between breaching medical privacy or ignoring data for rulemaking decisions altogether. Breaching a patient's medical confidentiality can have severe and wide-ranging consequences for patients' lives and livelihoods. Various groups have often tried to access patient data for retaliatory purposes. For example, when pork industry associates tried to access the identities of individuals who had participated in a study by the University of North Carolina Professor Steve Wing, about the harmful health impacts of hog farming, or when the Department of Justice tried to access names of women who had late term abortions for use in litigation challenging the Partial Birth Abortion Ban Act. Employees' health information can be and is used against them by employers as an excuse for termination or other poor treatment. Moreover,

when the medical confidentiality of research participants is breached, people are deterred from participating in research altogether. Medical confidentiality is a necessary element of modern medicine. Patients must feel safe telling their doctors the most intimate details of their lives. The expectation of confidentiality fosters openness and trust between doctors and patients and is crucial to the delivery of medicine and conducting clinical research. Courts recognize, too, the importance of medical confidentiality and privacy. In 1928, Justice Brandeis described the right of privacy as: "The most comprehensive of rights and the right most valued by civilized men." At least five circuit courts have recognized an individual's constitutional interest in or right to the privacy of their medical information. In Farnsworth v Procter and Gamble in the 11th Circuit, the court recognized that: "Even without an express guarantee of confidentiality, there is still an expectation, not unjustified, that when highly personal and

potential embarrassing information is given for the sake of medical information it will remain private." This right to medical privacy can extend to beyond publication of medical data to situations where medical information is available to those without a legitimate interest in it. See, for example, Tucson Women's Clinic v Eden in the 9th Circuit, where the court observed that even if safeguards against public disclosure were adequate, the lack of safeguards against release of information to government employees who have no need for the information could create a violation of the right to privacy.

The EPA claims, vaguely, that confidential data will be protected by redaction or de-identification. However, these mechanisms are entirely inadequate to maintain patient confidentiality. Latanya Sweeney, a Harvard Professor of Government and Technology, found in her study simple demographics often identify people uniquely that she was able to identify 87% of people in the United States with only their

gender, zip code and birth date. She has also found particular problems in patient confidentiality de-identification observing that in many healthcare data sets there will be unique data about people that can be used to identify them even when they are not explicitly identified in the data set. Sweeney found that even without identifying data in health data sets: "The remaining data can be used to re-identify individuals by linking or matching the data to other databases or by looking at unique characteristics found in the fields and records of the database itself."

Paul Ohm from the Georgetown Law School found in his pivotal work: *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, that using traditional, personally identifiable information focused anonymization techniques, any data that is even minutely useful can never be perfectly anonymous. These studies seriously undermine government claims that de-identifying data will provide adequate privacy for

patient data contained within research studies. Because of these reasons and those given before me, I strongly urge EPA to revoke the proposed rule immediately. Thank you.

MS. HUBBARD: Thank you.

MS. ANGLY: Hello, my name is Mary Angly and I'm interning for the organization Physicians for Social Responsibility and I've come to speak against the proposed rule, "Strengthening Transparency in Regulatory Science." Medical studies, clinical reports, and real-world field studies all include data and information that cannot be made public without violating confidentiality in patient protection laws. The proposed rule implies that these studies are not transparent because researchers necessarily suppress names and other identifying information about patients whose health information is relevant to study findings. Releasing individual participants' data to the public would violate confidentiality requirements legally mandated by the IRB and/or by HIPAA. By restricting these

studies, the proposed rule would essentially force the EPA to base many of its regulatory decisions on industry-sponsored studies and this rule could have huge environmental and public health implications. Despite a supposed scientific process, the funding source for a study can have significant implications on study findings. For example, in a review of research into the health effects of EPA an evaluation of 115 relevant studies was conducted in 2009. The review found that 94% of the publically funded studies found that chemicals have harmful effects whereas none of the industry-backed studies found these same findings. This is a huge disparity that cannot have occurred due to chance alone. Successful regulatory policies can have huge and quantifiable effects on exposure levels in human health. Biannually, the CDC collects data recording the blood and urine levels of 265 chemicals in people across the country. Longitudinal data can be used to visualize falling exposure levels and thus not measure the impact of a policy. For instance,

following the 1970's era lead regulations, 2009 blood lead levels were 8% of 1980 levels, which is a compelling example of a successful public benefit that occurred as a result of regulatory efforts. This is especially important when one considers that the detrimental effects of lead exposure are well known and well documented. Lead exposures leading to a blood concentration of 1 mcg/dL are correlated with an IQ loss of about 0.2 points. Each IQ point is estimated to raise worker productivity about 2%. Moral arguments aside, when considered from a population perspective, lead regulation has had huge economic benefits. A review of the EPA's archives shows that much of the original clinical research that formed the EPA's decision to regulate lead would have contained private health information. Under the proposed rule many of these studies would not have been able to be taken into consideration which is why it's so important that these studies are allowed to regulate future chemicals. Although lead specifically, and its health effects

are well known and well documented, my fear is that the future regulation of dangerous chemicals will be prevented due to the restrictive nature of this rule. Barring the use of major health studies under the veil of transparency will have huge and detrimental effects on the breadth and validity of the sources the EPA is able to consider when making regulatory decisions. Dangerous chemicals will not be able to be adequately regulated if the scientific processes are stymied.

I urge you to consider the health of this country when deciding whether or not to implement this rule. If the health implications are not enough to prevent the enactment, please consider the economic implications. The cornerstone of a healthy and productive population is a healthy environment. This rule would pose a serious barrier to the EPA's ability to effectively regulate. The power of landmark laws defined to protect human health such as the Clean Air Act, Safe Drinking Water Act, and Toxic Substances

Control Act, could be significantly undermined if this rule comes to fruition. Thank you for your time.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 31, Brenda Munive, and Speaker 32, George Thurston, if you would come to the speakers' table. Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the on-deck seating.

MS. MUNIVE: Good afternoon. My name is Brenda Munive and I am currently interning with the nonprofit organization called Physicians for Social Responsibility. I am a recent graduate of the University of California, Santa Barbara, with degrees in Environmental Studies and Communication. I am testifying today to voice my opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." I believe that scientific transparency is critical. Scientists, policy makers, and the public alike must all be able to trust and rely upon the scientific evidence that shapes our

society and the extent of human knowledge. However, I believe the EPA's proposed rule instead represents a serious misunderstanding of the institution of science. Furthermore, I believe that the proposed rule risks unnecessarily excluding valid scientific evidence from informing EPA policy, and therefore harms our fellow Americans through the creation of ineffective policies. The nature of the scientific field is unique. While most professions are motivated by political, economic or societal interests, scientists are motivated by seeking truth. Scientists perform research with the sole objective of uncovering the reality of how our world operates and gain status and recognition by succeeding in that goal. Top scientists are granted tenure or the assurance they cannot be fired from their position for whatever reason. Tenure guarantees scientists that they will not lose their position even if their research points to facts that are controversial or at odds with the current political societal climate. For these

reasons, ideally, they are not suspect to the same biases as most of the public. To prove this point it is helpful to look at the four norms of scientists as explained by renowned sociologist, Robert Merton. These are: Universalism, or the idea that truth applies to all regardless of belief; communalism -- the fact that all scientific knowledge belongs to the public; disinterestedness -- the fact that scientists are not concerned with the outcome of the research, only that it is factual; and organized skepticism or the tendency to be doubtful of any research to ensuring the deep truth. These norms describe the ideal foundation on which scientists and their research operate. Because of communalism, we can be confident that scientific research is as open as possible. Being intentionally secretive violates this ideal, so critical data must be accurately presented. This norm does not mean that all data is presented, however. Minute details, such as the identities of the subjects, are usually withheld in research studies of all

types to protect privacy and ensure participation -- or, encourage participation. It is important to emphasize that these omissions do not diminish the quality or the outcome of the research, but are made in the interest of the well-being of the participants. Because of this intrusiveness, the public can be confident that scientific research is virtually free of any bias favoring one agenda, and because of organized skepticism, scientific research is subjected to heavy review and fact checking before it is published in a scientific journal, so the public can be confident that published research is factually sound. Of course, there are exceptions to these ideals. For example, the norm of disinterestedness could be jeopardized if a scientist is hired by an outside party such as a company or noted member of the industry. The outside party introduces a monetary benefit and a desired outcome for the research, putting unconventional pressure on the scientist to fulfill the desires of whoever hires them. If the EPA's proposed rule is enacted, industry

funded research could comprise a disproportionate amount of what informs EPA policies, giving the industry, and not the scientific community, a large degree of input in shaping environmental protections.

Based on this knowledge, the proposed EPA rule is unnecessary. Mandating that underlying data be made public in order for scientific research to be utilized in informing EPA policies, attempts to increase transparency but fails to recognize that scientists already take thorough and exhaustive steps to assure their published research is unbiased, truthful and as transparent as possible. Research that does not meet these standards is rejected by the scientific community. The rule would restrict valid scientific data, particularly within health research where patient confidentiality mandates that identifying information remain anonymous. The result would be ineffective and harmful policies that could allow for practices and chemicals that genuinely harm our nation to remain rampant and unregulated.

This outcome would benefit no one and runs contrary to the EPA's mission of protecting public health and the environment. Furthermore, a healthy economy depends on healthy communities. For these reasons, I implore the EPA to reconsider enacting this rule. Thank you for this opportunity to present my testimony.

MS. HUBBARD: Thank you.

MR. THURSTON: Good afternoon, I'm George Thurston. I'm a professor at the New York University School of Medicine. Today I'm here representing the International Society for Environmental Epidemiology, the ISEE, which includes researchers who study environmental causes of ill health including ambient air pollution subject to the National Ambient Air Quality Standards, or NAAQS, promulgated by the EPA, as well as its standards for heavy metals, pesticides, drinking water and other environmental contaminants. As such, our members have supplied a substantial part of the research that is the basis of those standards. We strongly oppose the

implementation of EPA's proposed changes to the way that studies are considered in setting such standards. Based on an incorrect interpretation of transparency and replication in science, the proposed rule would deprive policy makers of the real-world epidemiological evidence based on real exposures of real people that have been, and will continue to be, vital for future considerations of EPA's health-based standards. I especially want to highlight for you the manuscript that I wrote 20 years ago entitled, "Band-Aiding the Release of Health Research Data: Issues and Implications," and the article is already posted on EPA's SAB web page. This article considered a similar proposal that was made in July of 1997 as an amendment to the U.S. House Appropriations Bill without any hearings. The problems I raised at that time are directly relevant to today's transparency proposal.

First, the increased potential for compromise of medical record confidentiality. As you've heard before today in a time of big data it's all too

easy to crack any de-identification process, especially when lots of publically available spatial and environmental data are matched to people in the study as they are in the studies that EPA considers. The solving of the Golden State Killer case, for example, is one example where a combination of two separate databases allowed de-identification of an individual. Second a loss of researchers' intellectual property. This can involve lost publications and academic career derailment. Third, the imposition of a government unfunded mandate. The USOMB has estimated that a similar law considered in the Congress, but that was never passed by the Senate, could cost the government up to 250 million dollars per year. There would also be the data prep costs to the scientists and their institutions.

Fourth, damage to future scientific research. When people no longer wish to enroll for fear that their medical data will be released, new scientific studies could be inhibited. Fifth, the

proposed rule will allow the EPA to ignore large portions of the scientific literature in decisions that are supposed to protect public health. In cases where key studies are excluded from the evaluation of environmental issue because of an inability to release study participants' private health records, the EPA may then ignore key scientific studies. This would diminish the evidence supporting protective health studies, potentially allowing the EPA to conclude that there's insufficient evidence to support proper health protective standards.

Sixth, the abuse of research data to undermine science credibility. This problem is likely the most dangerous aspect of this proposal. Past documented examples of abuse by consultants to a vested interest resulted when the state of Georgia set up an open records law and the R.J. Reynolds Company used it to obtain research data to attack study findings that the use of cartoon characters, such as Joe Camel, in tobacco advertising influenced children's product recognition. That

research was later validated in other studies but the damage was done and the physician involved left research for private practice. Thus, this data release approach has already been tried in the past and shown to be too easily abused by vested interests. There is also a tobacco connection to today's proposal. Just before the 1997 open data amendment was presented to the House, there was a December 1996 memo from the consultant of the tobacco industry, from Christopher Horner, laying out a similar strategy to address federal agency science with respect to second-hand smoke including a now familiar call for science transparency.

Finally, there's no need for this rule. Independent validation has already been conducted by groups such as the Health Effects Institute for air pollution studies, such as for the ACS and the Six Cities studies. Indeed, these are the studies mentioned by an earlier speaker, I believe it was Steven (sic) Milloy, and he incorrectly said that they were never released, they would never release

their data, and in fact they did release it. So, his testimony was incorrect. And whoever it was, I think it was Steven (sic) Milloy, but anyway, earlier speaker who said that Pope and Dockery had not released their data. They have done so and, in fact, it's an excellent example of how the system works. So, finally just to say such independent evaluations could easily be applied again to any new cases of concern for data validation without the above-noted risks. Thus, this dangerous rule seeks to needlessly solve a purported problem that just doesn't exist. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the speakers' table. Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you would come to the on-deck seating.

MS. MEYER: Hi. My name is Brittany Meyer and I am the Associate Director of Public Policy at the Michael J. Fox Foundation for Parkinson's

Research. I am here on behalf of the nearly one million people with Parkinson's disease in the United States who rely on the Environmental Protection Agency to safeguard their health and inform them about potential hazards in the environment.

For over the past ten years, we've learned a lot about the mechanisms of Parkinson's disease and now know that the condition is caused by both genetic and environmental factors. It is now very clear that when coupled with a genetic risk factor, exposure to several chemicals, most notably solvents and certain pesticides, can trigger the disease. Just eight weeks ago, a study out of Canada suggested that low-level exposure to pesticides disrupts cells in a way that mimics the effects of mutations known to cause Parkinson's. More research is needed to fully understand the mechanisms at work and how to prevent them.

Many of the studies used to identify risk factors for Parkinson's disease are investigated via large population-based epidemiology studies and will be

impacted by EPA's proposal. I am going to highlight one clear example- though along with my health and science colleagues here today, we can provide hundreds of examples of studies that could be impacted.

A 2009 study used GPS to estimate participants' well-water contamination exposure from agricultural pesticides. The results showed that consuming well water from a private well located in an area with historical pesticide use resulted in an increased risk of Parkinson's disease. Due to the nature of wells - typically serving a relatively limited number of people within a very small radius - the detail needed to perform the study renders proper de-identification impossible. All one needs to know is that a certain person lives near a particular well along with a demographic detail such as their age, gender, race, etc., and privacy is at great risk. Data from studies like this cannot be de-identified to the degree needed to protect patient's identification while still providing the

amount of specificity needed to help a scientist trying to replicate the results. Obtaining consent is not a solution. Some people make the choice to not disclose their Parkinson's diagnosis for a variety of reasons including privacy concerns, fear of prejudice or retaliation at work, and others. It is simply unreasonable to put people in the position of outing their diagnosis or to decline to participate in a study that could someday find a cure for their condition. Additionally, people who are willing to sign away their privacy and those who are not are different in ways we cannot predict or control for in study analysis.

The Michael J. Fox Foundation believes in open, reliable, and replicable science. We fund approximately 90 million dollars in research per year and hold our funded scientists to the highest standards. Our contracts require science studies to be peer reviewed and most require data to be as available as possible while protecting precious health data. We echo the call of our fellow public

health groups here today and the nearly seventy public health, science, academic, and medical groups who signed on to a joint statement calling for the rule to be abandoned for the sake of science and for our health. Thank you.

MS. HUBBARD: Thank you.

MR. SPANIER: Good afternoon, my name is Adam Spanier, S-P-A-N-I-E-R. I am a pediatrician and Associate Professor in the Department of Pediatrics at the University of Maryland School of Medicine. I'm also a member of the American Academy of Pediatrics, Council on Environmental Health Executive Committee. I'm here today on behalf of the American Academy of Pediatrics. The AAP strongly objects to EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposal will require EPA to ignore the best available, peer-reviewed scientific evidence on pediatric and reproductive environmental health, may violate patient confidentiality, and could dampen scientific processes by creating barriers to the use of

quality research in EPA science. Children and pregnant women are disproportionately affected by environmental pollutants and changes. Between 1990 and 2010, the Clean Air Act prevented over 160,000 premature deaths, 54,000 cases of chronic bronchitis, 130,000 acute myocardial infarctions, 1.7 million asthma exacerbations, 3.2 million lost school days and 13 million lost work days. Landmark academic studies guided EPA to implement policies leading to these dramatically positive outcomes. However, EPA's proposed rule will no longer allow EPA scientists to use much of the scientific evidence that's brought on these life-saving regulatory changes.

Scientific studies used by EPA to make regulatory changes are already rigorously examined prior to being published in peer-reviewed scientific journals. Scientists not associated with the research study must review the study design to ensure that it is scientifically sound before the study can be published. Many of the studies that inform EPA policy to protect the health of

children and pregnant women are based on IRB approved studies of the health of human subjects that require data confidentiality. Such studies involve observing the longitudinal effects on reproductive and child health from exposures to lead, particulate matter and other toxic substances. Replicating such investigations for the purpose of providing open access data for EPA to use would be morally unacceptable as it would require exposing children to lead, ozone and other damaging pollution. It would also not be ethical to exempt the study participants from data confidentiality protections. By requiring reproducibility the rule may also exclude many landmark public health studies that were so scientifically rigorous and resource-intensive that they could not be reproduced, such as the Framingham Heart Study, a 70-year-long cardiovascular epidemiologic study. Requiring reproducibility may also exclude studies done after landmark ecologic events such as oil spills and natural disasters. This rule does not improve

the scientific merit of the studies used for EPA policies, and, instead, creates significant barriers to EPA's assessment of past, current and future scientific work. This proposed rule contravenes EPA's mission to ensure that American pregnant women, children and families have clean air, land and water, and the AAP strongly urges you to not move forward with it. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you'll come to the speakers table. Before they speak I wanted to note that the time is now 2:39 and Speakers 35 and 36 are the last two speakers here to speak during the afternoon session. So, at this time if there's any speakers currently registered for the evening session but would like to speak now, if you would go to the registration desk we can get you a speaker number. Go ahead.

MR. MOULTON: Good afternoon, my name is Sean Moulton, Senior Policy Analyst at the Project On Government Oversight, a national nonprofit,

nonpartisan, government accountability organization. Thank you for the opportunity to speak this afternoon. I'm here to express my organization's strong objections to the proposed rule, "Strengthening Transparency in Regulatory Science," and urge the Agency to withdraw it. In the proposed rule the Agency notes that the best available science must serve as the foundation for EPA's regulatory actions. It is hard to argue with that fundamental principle, but this policy won't make scientific information better, nor more available. Instead, the new rule will often mean the best available science is off limits to the Agency, create delays in rulemaking and result in greater litigation.

I'd like to focus primarily on the rulemaking process and first raise serious concerns about the insufficient development process that produced this rule, a rule that fundamentally changes what information can and cannot be used in future rulemakings is a major undertaking and requires a great deal of certainty and evidence, yet this

proposal offers no clear explanation of the precise problem, no supporting evidence, no studies establishing that EPA has an information problem, nor citations that the proposed standard has been successfully used before or that EPA understands what its impact will be on the regulatory process when implemented. Even if the Agency truly believes there is some deficiency in its information policies and procedures, this proposed rule is premature. The starting point should be conducting studies of the issue to better understand the scope of the problem, if there is one, and the best way to improve transparency of regulatory science. The Agency should allow the Science Advisory Board to fully investigate and offer specific recommendations before moving forward with any proposed rule. There are any number of steps that the EPA should be completing before rushing into a formal rulemaking. The incomplete foundations for this rule reveal themselves in the vague language and unclear standards. The rule does not specify how

the new standards will be implemented, what mechanisms will be made available to allow publishing of more detailed data. More importantly the rule doesn't address how it will fit into the legal requirements the Agency has under the Administrative Procedure Act or other environmental laws.

The proposed rule is being done at EPA's discretion with no statutory authority backing it up. So, should this policy come into conflict with statutory requirements under existing law, those laws take precedent, and laws governing rulemaking have a number of requirements that this proposed rule would be in conflict with. The Administrative Procedure Act makes clear that an Agency cannot engage in arbitrary, capricious actions or decisions in its rulemaking; while the Agency has authority in its given area, that authority is not absolute. The Agency must have clear and strong justifications for its actions. Given the lack of supporting evidence for this policy or a statutory requirement from Congress,

EPA will be hard pressed to prove that this untested standard is not arbitrary. Even if the rule isn't immediately dismissed under the APA, the EPA's requirements under other laws, such as the Clean Air Act, that it consider all available, or best available, science in rulemaking and this policy would be in direct conflict with those. If the Agency seeks to apply this new standard in areas ungoverned by such statutory requirements, it will result in a confusing patchwork of standards where a study may be available for consideration under a Clean Air Act rule or a TSCA rule, but that same study would not be considerable in another rule.

I wanted to note in a case before the U.S. Court of Appeals for D.C. around the availability of air quality data study information, the court addressed this very issue, stating that, "If the EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant

scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment." Placing large portions of scientific research off limits simply goes against common sense. EPA should be able to use any and all available information to produce the best, most up-to-date rules. If a study is unreliable or flawed in some way, then the Agency can decide that based solely on that study's merits, and sometimes even flawed or partial studies can offer important insights that the EPA should benefit from.

We strongly urge EPA to withdraw this rule. Thank you very much for your time.

MS. HUBBARD: Thank you.

MR. BERGMAN: I'm Andrew Bergman, and I'm speaking today as the Special Environmental Advisor at the Project On Government Oversight, but I'm also currently a Ph.D. student in applied physics at Harvard University.

While the proposed "Strengthening Transparency in Regulatory Science" rule uses the words

"transparency" and "reproducibility" to project lofty goals, it's real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process. I'm here today to urge EPA to withdraw this rule. My colleague, Sean Moulton, has just addressed how the proposed rule conflicts with the EPA's regulatory process, and the statutory requirements underlying that process, but the rule will also have a direct impact on how the EPA approaches science.

The rule fails to properly address its two key considerations that will have a major impact on how it is implemented. First, the rule states that data relied on in making regulations must be made publically available, but it doesn't suggest a mechanism for how personally identifiable information or confidential business information would be handled.

This is an incredibly important issue, as so many studies that EPA uses rely on this type of confidential data. Yet it's reasonable to conclude

from the rule that, if it goes into effect, the EPA will no longer be able to use most longitudinal human health studies to craft public safeguards, even though those studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity. Instead, they will be left with industry studies that more often use animal test subjects, which don't have any personal privacy concerns.

Second, while the rule refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' reproducibility, which has a wholly different meaning in a scientific context. But because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule intends the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings.

The Agency uses many studies, however, such as

those that link leaded gasoline to brain damage in children or a study that found a link between fine particulate air pollution and premature deaths, that examine dangerous real-world exposures and cannot, of course, be safely repeated. Just because they can't, or shouldn't, be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future. Without knowing the details of how these two provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. We can conclude that the result will be that large swaths of studies will be arbitrarily ruled out for use in future rulemakings.

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially. The CBO found that a policy very similar to the proposed rule,

when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding--a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary." The three-judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying

them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all. Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation?

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made

in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed, "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule. Thank you for your time and for the opportunity to comment on this important proposal.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 37a, Emma Glidesgame, and Speaker 38a, Jyotsna Pandey if you would come to the speakers' table. Speaker 39a, Patricia Cohen speaking on behalf of Tracy Woodruff, if you would come to the on-deck seating.

MS. GLIDESGAME: Good afternoon. My name is Emma

Gildesgame, G-I-L-D-E-S-G-A-M-E. I'm a Master of Environmental Management student at the Yale School of Forestry and Environmental Studies, and an intern with the National Parks Conservation Association. My comments today are my own. I'm here to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule, that would censor science and threaten the health of all Americans. Last week, many of us in D.C. awoke to alerts warning of potential contamination in our water system. We were told to boil water before drinking or brushing our teeth or to avoid tap water altogether. For those few days, stores sold out of bottle water, Starbucks stopped selling coffee, and public pool splash pads and water fountains went dry. In the face of an urgent public health risk we did not censor the science that told us that contamination in our water is a threat. To know that clean water is important we didn't need the health records of every person who participated in landmark studies that helped us

understand the effects of contaminated water on our bodies and brains. The science is real. It's not secret, it's been repeated. It's been peer reviewed, analyzed and reaffirmed by generations of experts.

Just as the residents of D.C. took precautionary actions to protect ourselves and our loved ones in the face of a potential public health threat, the EPA must be allowed to use the best available scientific data to accurately assess environmental and public health threats to protect all Americans. The Clean Air Act, Clean Water Act, Safe Drinking Water Act and other historic laws that helped the United States become a leader in environmental protection recognized something that we forget far too often: Human health is environmental health. They are one in the same. Pollutants in the air travel hundreds of miles to become pollutants in our lungs. Contaminated soils grow contaminated food. Toxic river water becomes toxic drinking water. At the same time, clean air builds stronger kids. Healthy rivers,

lakes and watersheds build healthy communities. Good environmental and public health policies rely on a strong backbone of good science. The proposed rule would eliminate many credible, respected, long-standing, peer-reviewed, scientific studies from EPA consideration because they rely on confidential health information which cannot be made public. This proposal allows politically appointed regulators to pick and choose which studies they want to consider and would force scientists to choose between their ethical obligation to protect their subjects' privacy and the obligation to contribute knowledge to apply to regulatory science. Using good science to make strong policy has made America great for decades. The EPA and other agencies have kept countless Americans healthier, safer and more prosperous by using science to inform conservative, proactive protections for human health and the environment. We have protected historic and cultural monuments like the Jefferson Memorial, Statue of Liberty and even the Capitol

Building from the corrosive power of acid rain. We have reduced smog and air pollution in national parks like Great Smoky Mountains, Joshua Tree and Yosemite. We have improved water quality from the Great Lakes to the Everglades. Thanks to the EPA, my peers and I were born into an era of healthier air, cleaner rivers, and safer drinking water than our parents. I hope that someday my children can say the same, and that is why today I am joining thousands of scientists and public health professionals all over the country in speaking out against this rule and asking you to stop it in its tracks. We are all counting on you to listen to the sound and transparent science the EPA has used for decades and we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MS. HUBBARD: Thank you.

MS. PANDEY: Good afternoon, my name is Jyotsna Pandey, and I'm the Quality Manager for the American Institute of Biological Sciences. My

organization appreciates the opportunity to comment on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." We thank EPA for extending the initial 30-day public comment period and scheduling this public hearing on the proposed rule. We support the objective of increased transparency in the rulemaking process. But, the proposed rule is inadequately defined and thus itself lacks transparency and appropriate public protections. We request the EPA rescind the proposed rule and initiate an open process for gathering the information required to more thoroughly articulate the proposed rule. Any proposal to increase transparency in the regulatory process must not arbitrarily exclude important scientific information from the decision-making process, nor can personal information about individuals, such as genetic information or health status be sacrificed. A failure to protect these data will hinder future scientific investigations of people who refuse to participate in recent studies if they are not

confident that their most personal information is protected. Importantly, scientific journals take steps to protect personal information. They are not aware of any secure way to mask or protect personally identifiable information in the public domain and therefore think that any rule requiring this information be made public is needlessly risky. These data are important, however, to informing the decision-making process and should not be excluded for rulemaking processes because they are not publically disclosed.

As far as this request for comment, EPA has solicited input and measures to "provide protected access to identifiable and sensitive data." This is a significant issue and one that EPA should fully understand prior to moving forward with any new rule. Time and expertise are required to identify and properly evaluate the feasibility, cost and effectiveness of potential actions. It is unlikely that EPA can effectively gather and evaluate this information in the time prescribed by the proposed rule. We recommend that EPA

initiate a formal request for public comment on this issue alone and use what it learns to help inform and guide any potential future rule on transparency.

High-quality, curated and vetted mega data are generally required for someone else to appropriately reanalyze or use data such as those that could be made available by the proposed rule. The proposal is silent on meta data standards and practices. This is a significant challenge and another major problem with the proposed rule. We support EPA's goal of conducting independent peer reviews of the science and data used to inform regulatory decisions but thinks the section lacks adequate specificity. Who will conduct and manage the peer review process? Will these reviews be managed by the Office of Research and Development or by the various regulatory offices within EPA? Does EPA have appropriate staffing, expertise and resources to manage these peer reviews? We recommend that EPA partner with scientific organizations and professional communities to

administer and manage these reviews. Such outsourcing and partnerships will help to ensure that EPA gains access to independent and highly qualified experts and to promote greater public confidence in the independence of these peer reviews. This kind of process for managing peer review will also allow EPA to more cost effectively, nimbly and rapidly conduct reviews as it will not require EPA to substantially increase staffing for the remaining reviews. Such a process would also provide EPA with greater capacity to conduct reviews on time skills that do not needlessly delay regulatory and rulemaking schedules. After reviewing this proposed rule the AIBS respectfully urges EPA to rescind the current proposal. We ask that EPA initiate a new transparent and interactive process with the scientific, public health and environmental management communities, as well as other appropriate stakeholders, to identify responsible and viable approaches for promoting greater understanding of the science and data used to

inform EPA decision-making. Thank you for your consideration of our request.

MS. HUBBARD: Thank you.

MS. STOBERT: Patricia Koman, if you'd come to the speakers' table.

MS. KOMAN: Good afternoon. My name is Patricia Koman, spelled K-O-M-A-N. I am speaking on behalf of Dr. Tracy Woodruff, W-O-O-D-R-U-F-F. Dr. Woodruff is a professor in the Department of OB/GYN and the Director of the Program on Reproductive Health and the Environment at the University of California, San Francisco. Dr. Woodruff is a PI, or Principle Investigator, for a Children's Environmental Health Center and she, along with 15 other principle investigators of other Children's Centers, have submitted comments to the EPA about this proposed rule in writing. They are concerned that the proposed rule will adversely affect EPA's ability to use science in decision-making and ultimately negatively influence protections for children's health. Research from Children's Centers contribute

significantly to the foundation of science that informs and supports the Agency's ability to protect the public health. The National Academy of Sciences highlighted that Children's Centers have led to an improved understanding of the environmental impacts on child health and development. Children's Centers research identified the critical contributions of environmental exposures to asthma, obesity, ADHD, cancer, autism and other childhood illnesses. This research has led to new direction, treatment and prevention strategies for these diseases including informing EPA standards for cleaner air which has improved the quality of life for children. Collectively, we have research data from thousands of participants across the country, including some of our most vulnerable populations, children and women in communities of color. To not use or consider studies that do not comply with the proposed rule is inconsistent with scientific principles and evidence-based policy and this would put the public's health at risk

from toxic chemicals. Institutional review boards require that we protect the privacy and confidentiality of our participants, but institutional review boards' requirements conflict with this rule's mandate to publically reveal individual level data. Data masking, coding and de-identification techniques have limitations, because re-identification of participants is still possible. We are especially concerned that the rule inappropriately codifies specific data analysis approaches such as dose response modeling and other scientific decisions that should be made on the basis of scientific judgment and empirical considerations. This will hinder scientific inquiry and lead to inaccurate results. As scientists, we value open science but the mandates laid out in this rule will not improve data sharing, replicability or transparency. Instead, implementation of this rule, especially retroactively, could lead to EPA excluding numerous relevant studies from policy decisions to the ultimate detriment of children's health. We

urge EPA not to move forward with this proposed rule.

Finally, I want to comment about this public hearing and its lack of access to all stakeholders. By not providing the ability to make comments remotely or virtually, EPA limits the public comments to those that have the financial resources to travel to Washington D.C. and limits the participation of populations that are going to be most affected by this rulemaking. This undermines civic engagement and conflicts with the principles of a fair democracy. This is not a technical issue, as U.S. EPA has made virtual public comment in the past.

Finally, we urge EPA not to move forward with this proposed rule. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: It's now 3:02 p.m. This was our last speaker for this session that we know of. We are going to repeat the request that if there is any speaker that has registered but is registered for the evening session, if you'd like to speak

now go to the registration desk and you will receive a speaker number for this session. We're going to wait a few minutes and see if there's anybody that decides to speak now. Otherwise, we will break until the 4:00 session starts.

MS. HUBBARD: And if I could just make a quick announcement, we do have a member of Congress who is on his way to speak who should be here shortly, so we won't go into recess quite yet, so if everyone could just remain in their seats if you're interested in hearing him speak, otherwise feel free to go on and head on out and then we'll go into recess after that.

MS. STOBERT: Sorry, Peter Ferrara, speaker 40a, if you would come to the speakers' table?

MR. FERRARA: Good afternoon. My name is Peter Ferrara, that's F-as in Frank, E-R-R-A-R-A. I'm the Senior Fellow for Legal Affairs at the Heartland Institute. We submitted our comments during the comment period online in response to the notice for public comment in rulemaking posted on April 30, 2018. EPA proposes the rule I am

commenting on intending the strengthen the transparency and integrity of EPA regulatory science. The proposed rule provides that EPA should ensure that the data and models underlying scientific studies pivotal to EPA regulations are publically available in a manner sufficient for independent validation, especially concerning regulations for which the public is likely to bear the cost of compliance. We applaud this proposed rule and find that governing statutes and executive orders, not to mention the basics of the scientific method, authorize the proposed rule and indeed have long required it. In not following the proposed rule in the past, EPA has been flouting the governing statutes and executive orders, departing from the scientific method and abusing its authority. The proposed rule provides that for science pivotal to significant regulatory action, EPA will ensure that the data and models underlying the science are publically available in a manner sufficient for validation and analysis. This new policy is needed because EPA admits to

having not previously implemented these policies and guidance in a world-best, robust and consistent manner.

Examples where EPA previously has fallen short include the public health research used to implement and defend the PM2.5 particulate matter standards, the corporate average fuel economy standards, the ozone standards and carbon dioxide standards. EPA's admitted reliance on secret science occurs at a time when the publications *Nature*, *PLoS*, *Science*, *The Economist* and other report half or more of published research on public health issues cannot be replicated. This replication crisis is genuine and even more broad and critical than the sources cited by the EPA for this proposed rule are willing to admit. A scientific publishing industry has been created by lavish government funding of politically directed research. Examples of this include supposedly scientific studies finding human impact on the climate or an association between ozone and climate. It may take generations before the

effects of this corruption can be overcome. The root cause of EPA science malfunction has been corruption of EPA's peer review process. Peer review for the EPA has become power review with insiders typically armed with millions of dollars in government funding acting to censor and exclude scientists who disagree with the reigning political agenda. That perverts the whole point of peer review, turning it into a tool used to shut out anyone who disagrees, instead of a process forcing scientists to defend their work against critics. The more widespread replication crisis is proof that this disease has affected most of the world's leading science journals and even its National Academies of Sciences. One scientific finding that has been suppressed by the corruption of peer review was just singled out by EPA in its call for comments, is evidence of non-linearity in the concentration response function for many pollutants. The entire regulatory model is precariously perched on an invalid assumption of linearity and the resulting scientific crisis

continuing to build must now be openly faced, removed and regulations based on such science malfunction, or even outright corruption, must be revised and repealed entirely. EPA's new policy of scientific integrity and transparency should be applied to computer climate models that currently prevail in EPA's funded published and cited climate science. The continued use of default models, not consideration of alternatives or model uncertainty create a false scientific justification for EPA actions, policies and regulatory burdens.

So, we applaud this new proposed rule and encourage the EPA to implement it rapidly.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 41a, Liz Hitchcock, and Speaker 42a, Benjamin Kirby, if you would come to the speakers' table.

MS. HITCHCOCK: Good afternoon, my name is Liz Hitchcock, and I direct Safer Chemicals Healthy Families. We lead a coalition of hundreds of local, state and national groups. This variety of

groups of labor, consumer, parents, educators, scientists, health care providers, health-affected and others shares the concern about the growing recognition of the links between our exposures to toxic chemicals and the increases in cancers and other chronic illnesses and in learning and developmental disabilities, and we share a commitment to reducing and eliminating exposures to toxic chemicals in our homes, our places of work, and the products that we use every day. I thank the Agency for responding to the large number of public comments that objected to the length of the initial comment period by extending it and for scheduling this hearing.

Safer Chemicals Healthy Families joins a long day of voices in opposition to this proposal. Many of our coalition partners and a number of respected scientists have offered strong cases for withdrawing the proposal already today and I thank those speakers for their comments and will try to keep my own comments brief.

The proposed rule is irreparably flawed and

misconceived. In the name of transparency it will prove needlessly burdensome, requiring unnecessary and costly procedures of EPA scientists that are counter to the Agency's longstanding application to base public health decisions on the best available science. Under this proposal without a guarantee of full public access, the study will be considered unreliable and will play no role in assessing a chemical's health effects on human health. This ignores the many ways in which the scientific community, regulators and the public have traditionally determined the quality and relevance of study results. It also disregards the way that hard-working EPA science professionals have taken seriously their charge to use the best available science in their decision-making. Safer Chemicals Healthy Families played a key role in the reform of the Toxic Substances Control Act which requires that EPA use the best available science in the review and management of toxic chemicals. As EPA begins to review the tens of thousands of chemicals already on the market we

are concerned that they be able to take into consideration all information that is reasonably available. For the fence line communities that have been harmed by their exposures to chemicals, for the families who have lost loved ones to asbestos-related diseases, for the firefighters exposed to a soup of toxics as they protect our communities, and to children who are born pre-polluted by a range of industrial chemicals, the stakes are high for these evaluations. EPA scientists working on risk and hazard assessments collect and review thousands of studies. Published reports of these studies typically do not include all the underlying data. This proposal would add the burdensome requirement in such cases that EPA contact the researcher, determine the nature and extent of the underlying data, and put in place a mechanism for the public to access the data. Many before me have called this proposal a solution in search of a problem, but it bears repeating. In proposing this rule EPA leaders have painted a stark picture of EPA

reliance on so-called secret science developed behind closed doors, but is this really so? EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record, even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review and members of the regulatory community are free at any time to replicate studies they deem flawed or to independently seek access to underlying data and reanalyze them. In short, the so-called problem that the proposed rule seeks to fix is largely fiction.

In conclusion, EPA should withdraw this proposed rule. The public health stakes are just too high. Thank you.

MS. HUBBARD: Thank you.

MR. KIRBY: My name is Ben Kirby. I'm an environmental engineer with a doctorate and

master's degree in environmental engineering from Virginia Tech and George Mason University respectively. I'm representing Hall and Associates, and environmental consulting firm in Washington D.C. We support the application of this rule to EPA's environmental impact analyses, particularly TMDLs, or Total Maximum Daily Loads, and NPDES or National Pollutant and Discharge Elimination permits under the Clean Water Act. These legally binding permits include ethylene limits for wastewater treatment facilities for pollutants such as lead, mercury or phosphorus. Slight alterations in these permit limits can cost a single wastewater facility tens of millions of dollars, the cost of which is passed on to individual local rate bearers. These permit limits are supposed to be derived in a manner similar to dose-response relationships as mentioned in the rule where, for example, a lower level of the pollutant in the discharge will result in a measurable increase in receiving water quality working with health. However, we have

dealt with instances throughout the country where environmental agencies have based regulations on publically unavailable data, outdated science or faulty science, even in the face of data or studies which indicate stringent permit limits imposed by these agencies are not anticipated to result in any quantifiable environmental or human health benefit despite the cost. We hope that this rule would remedy these shortcomings.

We also strongly support the use of independent expert peer reviews as an additional level of review for fiscal regulatory science. Our firm has been involved in independent peer reviews of various Clean Water Act related EPA regulations which have concluded that the technical basis for EPA's regulations and permit limits were scientifically indefensible. Had no peer reviews occurred, these regulations would have imposed hundreds of millions of dollars of wastewater treatment costs to rate bearers with no anticipated benefit. As a science-based Agency applying science-based statutes it is critical to

both receiving water quality and rate payers throughout the country that these permits and regulations are based on sound science and not speculation.

In this regard, we support application of EPA's proposed rule to Clean Water Act regulations.

Thank you for the opportunity to come.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker A, Dan Lipinski, you are now invited to speak at either the table or the podium.

MR. LIPINSKI: Good afternoon, I'm Congressman Dan Lipinski of the Third District of Illinois. I'm here to ask the EPA to rescind the proposed rule. The origins of the rule are in the 2014 House Bill called, the Secret Science Reform Act, which I voted against in that year and again in 2015, and when it was reintroduced as the Honest Act in 2017. The goal of these bills and of the proposed rule, contrary to its name, is to limit availability of science to inform regulatory decision-making. I'm disappointed to see the

Trump administration circumventing the will of Congress, attempting to administratively implement policies that cannot pass through the Legislature. On June 7th of this year, I joined 102 of my colleagues from both political parties in sending a letter to then Administrator Pruitt urging him to withdraw the proposed rule. My comments today build on that earlier commentary and expand on my opposition to this misguided policy.

EPA's admission, as it appears on the Agency website, is to protect public health and the environment and to ensure that national efforts to reduce environmental risks are based on the best available scientific information. The proposed rule works in direct opposition to that mission by requiring that the data underlying the scientific studies used in informed regulatory actions are available to the public. The proposed rule will exclude vast quantities of valuable research including that based on personal health data, confidential business information, and even older studies whose authors or data sets are no longer

available. In some cases, the rule will require the exclusion of the best available scientific information. To make matters worse, this rule would grant the administrator wide latitude to exclude studies from its provisions, enabling him or her to cherry pick studies in order to affect the outcome on the rulemaking process. There is no basis in any of the statutes under which EPA operates for giving an administrator such broad authority to choose which science is used in rulemaking.

Let me give an example of how the proposed rule could affect a future EPA rulemaking. EPA is planning to update its lead and copper rule in the near future the rule that limits the levels of these metals in drinking water. This update cannot come soon enough. We all know about the drinking water crisis in Flint, Michigan. Chicago and Washington D.C., as well as many other cities around the country, are finding troubling levels of lead in drinking water right now. Most of what we know about the health effects of lead exposure

comes from older studies of children with high levels of lead in their blood. Yet these studies may be excluded from consideration, both because their data are not publically available and because it would be unethical to replicate them. As a result, it is possible that an Agency could conclude that there is no evidence that lead is bad for you and, therefore, does not need to be updated. This would be a tremendous mistake. I have spent my career in Congress working to enable science-based decision-making in government. The proposed rule represents a significant step backward and I urge the Agency, in the strongest terms possible, to rescind it. Thank you.

MS. STOBERT: Speaker 43a, Mahealani Daniels. If you'd come to the speakers table.

MS. DANIELS: Good afternoon. My name is Mahealani Daniels and I'll spell that M-A-H-E-A-L-A-N-I, D-A-N-I-E-L-S. I would just like to thank you for allowing me the opportunity to share my comments in opposition to the EPA's new policy on so-called transparency. The EPA must utilize

the best available science to inform its actions in the creation of environmental and public health laws. Judicial precedents establish that the best available science is all existing scientist evidence relevant to the decision. In further supporting these precedents, the EPA's own regulations state that the best available science would be information that the EPA possesses or could reasonably generate, obtain or synthesize, whether or not that be information that is confidential business information that is protected from public discourse. While increasing transparency and ending an era of secrete science are two statements that publically resonate as appealing advances, when digging deeper it is clear that the EPA's implementation of these standards would do just the opposite and would actually violate judicial precedent as well as the Agency's own regulations. A majority of confidential health data can't be used with the EPA's new standards of transparency, thus limiting the scientific evidence they could use to inform

studies and standards. Since personal health data informs the production of environmental laws that protect public health, it's exceptionally important that the EPA continues to use it. For example, a recent study released by MIT demonstrates that 200,000 early deaths occur every year in the United States as a result of air pollution. Utilizing data on patients' health is not only necessary to establish the aforementioned research, but is also necessary when the EPA goes to set standards on environmental and pollution regulations that affect the lives and health of millions of Americans. I am hopeful that just as a majority of Americans are guided by their own personal values to abide by the laws established by our government, the EPA will too decide to function under judicial precedents and be guided by its principle to utilize the best available science. And with that, I thank you so much for your time.

MS. STOBERT: Thank you. I believe that was the last speaker for this session, so we will recess

now and resume the hearing at 4:00 p.m. Thank you.

[Off the record 3:26 p.m.]

[On the record 4:00 p.m., Evening session. Substitution of panel members.]

MR. RODAN: Okay, so welcome back at 4:00. Let us commence session three of this public hearing. Hello and thank you for coming. This public hearing is now in session. My name is Bruce Rodan and I am in EPA's Office of Research and Development. I will be one of the hearing officials of this two-hour period. Lou D'Amico, also from the Office of Research and Development will be joining me. We also have Nanishka, Lauren and Lesley from SC&A Incorporated helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of

the administrative record on which EPA will base its decision. Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under authority of 5 U.S. Code 301 in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA received your comments in an orderly fashion. Although EPA panel members may ask clarifying questions the intent of this hearing is to listen to your comments, not to discuss or debate the proposal.

Now for a few housekeeping items and ground rules. Please refrain from interrupting speakers or asking questions. Shouting and noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies.

For everyone's awareness, this hearing is open to

the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing. There was no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again, so please be aware of time and the rain outside. If you'd like to make an oral comment in today's hearing and did not pre-register to speak, please see the hearing staff at the registration table positioned at the entrance of the room. If you would like to provide a written comment to the official record, you may hand submit it to the EPA staff today or mail, fax or email your comment. See staff at the registration table for instructions on how to submit written comments. There is a comment box at the registration table where you can leave hard copies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments

it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision. EPA has extended the comment period. Written comments must have been received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making comments that are not related to this action. EPA will not provide responses during the hearing, rather EPA will prepare a written summary of the comments received that includes responses. The Response to Comments, RTC, document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered. The hearing is being recorded by a court reporter who will be preparing a verbatim record of the hearing. Please speak clearly and slowly into the microphone so that the court reporter can record

your comments accurately. A copy of the transcript will be placed in the docket. The hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier, and is divided into three sessions: 8:00 a.m. to 12:00 p.m., 12:00 p.m. to 4:00 p.m., and this session 4:00 p.m. to 8:00 p.m. Public restrooms are located down both sides of the hall and we have staff to escort you. Please note the location of the emergency exits.

Please take a moment to silence your cell phone (I've done that). Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For the current 4:00 p.m. to 8:00 p.m. session, the speaker sticker collar is blue. Speakers will be called to the speakers' table located directly across from the EPA panel

members' table in pairs by their speaker number. When it is your turn to speak, please come up to the table and watch your step. State and slowly spell your name for the record, and if you are appearing on behalf of someone or an organization. If you are not in the room when it is your turn to speak I will recall you after all other speakers have made their oral comments. Each speaker will be allotted five minutes for remarks. Elected and appointed government officials may be provided additional time since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system or speaker timer consists of green, yellow and red lights. When you begin to speak, the green light will come on to indicate you have five minutes to speak. The yellow light indicates that you have one-minute left to speak. When the red light appears your five minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap up your testimony. So, let's begin.

Speakers Numbers 1 and 2 in the afternoon session, please come forward and take a seat at the speakers' table. We will start with Speaker Number 1. Again, please speak directly into the microphone and state and spell your name for the record.

MR. SHIPPS: Thank you for this opportunity to provide public comments on EPA's proposed rule, "Strengthening Transparency in Regulatory Science." My name is Karl Shipps. That's spelled K-A-R-L, S-H-I-P-P-S. I live in New Carleton, Maryland, and I'm speaking as an individual. I am not employed by EPA or an EPA contractor, I am simply a very concerned person. I am a Navy submarine veteran, a grandfather, and have a master's degree in applied physics from the Johns Hopkins University. Because my time is limited I will confine my remarks today to three observations about the proposed rule and two recommendations.

My first observation is this: The proposed rule is based on a faulty premise, namely that only

studies whose underlying data are publically available sufficient to support replication should be considered by EPA as it develops regulations governing clean air, clean water and exposure to toxic substances and pesticides. The rule's premise, which was also the premise of the Secret Science Reform Act and the Honest Act, cannot stand. There are valid peer-reviewed studies that should be included in EPA's regulatory work even though their underlying data sets cannot be released to the public. Two of the most widely known are the Harvard School of Health's Six Cities Study, and the American Cancer Society's Cancer Prevention Study II. Those studies were revalidated by the Health Effects Institute in July of 2000 using an independent oversight board and a competitively selected analysis team. They remain valuable today. Since the proposed rule is based on a faulty premise, I recommend that it be withdrawn. A new rule addressing concerns about reproducibility and replicability should be developed in public with participation by the

scientific community, the environmental community and industry. The rule developers should avail themselves of the results of the ongoing reproducibility and replicability study being conducted by the National Academies of Sciences. That study will report in December 2018. Perhaps the EPA will not take my recommendation to withdraw the proposed rule. In that event, my second observation is germane. My second observation is that the EPA administrator is given extraordinary powers under Section 30.9 of the proposed rule for new EPA regulations or for regulations undergoing periodic update, the administrator could waive or not waive the provisions of the rule. This puts potentially thousands of studies underpinning EPA's regulations at risk of being discarded out of hand at the administrator's whim. The result would not be the best science and it would reduce public confidence in EPA rulemaking, not increase it. Based on that prospect, I recommend what the Texas Commission on Environmental Quality recommended,

namely to give governing authority for granting exceptions to the proposed data Transparency Rule, as well as the oversight of raw data collection, storage and access, to an external entity or entities to ensure independence and objectivity. You can see Docket comment EPA-HQ-OA-2018-0259-2426.

My final observation is that the scientific community was not consulted as the proposed rule was prepared. Even EPA's own Science Advisory Board was not consulted, learning about the rule only through press accounts and publication in the Federal Register. The joint statement on the EPA proposed rule and public availability of data in the 30 April edition of *Science* disagrees with the proposed rule. EPA should heed the concerns being voiced by the scientific community. Thank you for your attention.

MS. WHITE: Good afternoon. My name is Dr. White, W-H-I-T-E, on behalf of the American Chemistry Council's Formaldehyde Panel. I appreciate the opportunity to provide feedback on EPA's proposed

rulemaking. Utilization of transparent, objective and modern scientific approaches to draw conclusions regarding human health risks is critical to developing sound regulatory decisions. Throughout the EPA the application of scientific information to underpin regulatory activities has often been inconsistent and unclear, leading to concerns regarding how the Agency incorporates the best available science, evaluates the quality of that science, and applies 21st century knowledge concerning cause and effect. The panel has regularly met with EPA scientists related to the IRIS program regarding its subjective use of available science and resistance to moving away from default linear low-dose extrapolations, even when published scientific data support other modeling alternatives, including threshold-based approaches. This stance has often led to the generation of EPA values that are below natural background levels and not indicative of human health risks associated with real world exposures. Perhaps the most telling example can be found in

the case of formaldehyde, where a draft IRIS assessment sets values suggesting that human breath could pose a cancer risk. Formaldehyde has been the subject of scientific study for years and large bodies of evidence show that the levels of formaldehyde most people encounter on a daily basis do not cause adverse health effects, a conclusion reached by several international agencies using alternative models other than a default linear modeling approach. The evidence demonstrates the biological implausibility of any relationship between formaldehyde and leukemia, a threshold mode of action for any potential adverse health effects, and the importance of mode of action information for understanding potential impacts. We are encouraged by the Agency's proposed rule's recognition that there is growing empirical evidence of nonlinearity and that the use of default models without consideration of alternatives can obscure the scientific justification for EPA actions. This acknowledgement by EPA is especially relevant to

formaldehyde given the several decades of published literature illustrating preserved thresholds for both noncancerous and cancerous status.

In addition to the significant research and the development of a biologically-based dose response model for formaldehyde that also integrates the available science and provides results inconsistent with default linear dose response modeling approaches typically apply for carcinogenic end points. The importance of using nonlinear and biologically based dose response modeling, when the published data supports it, cannot be overstated. In this review of a 2010 draft IRIS formaldehyde assessment, the National Academy of Sciences noted the development of several models to evaluate the risks associated with formaldehyde exposure and recommended that alternatives to EPA's default linear low-dose extrapolation approach be considered.

In addition to incorporating modern scientific knowledge, we also recognize the importance of

adequate transparency in data access and ensuring regulatory decisions are based on high quality and reproducible data. For more than a decade, the panel has conducted scientific research engaged directly with EPA's IRIS program to understand the scientific information being relied on to draw conclusions regarding potential for health effects. The panel has experienced considerable difficulty in understanding what data is being relied on and how the Agency has ensured the highest quality and most relevant science is informing its decisions. Importantly, in multiple instances, sometimes after years of requests, once the underlying data was made available, it was found to have significant methodological and quality issues. In several cases, the findings, when reevaluated, did not support the original study's conclusions. The issues identified were not minor and highlight the need for greater transparency and for EPA to have a mechanism in place to evaluate the quality and reproducibility of the data being relied upon for decisions.

One notable example involved over six years of repeated requests to access all the relevant data from a National Cancer Institute study which was relied upon by the IRIS program to draw conclusions regarding formaldehyde and leukemia. The data were requested from NCI for the purpose of validating the author's conclusions and the evaluation of that underlying data found that changes reported by the study authors were not exposure dependent and they did not follow their own stated protocol. As demonstrated by formaldehyde example, when the data access is limited and modern scientific approaches aren't used to move away from default assumptions, the results can be conclusions that lack scientific rigor and potentially provide the public with an inaccurate picture about everyday chemicals which have been used safely for years.

I hope that you find these comments useful and I will provide a detailed set of comments by the August deadline.

MR. RODAN: Thank you. I believe we have another

speaker.
MS. HALL: Right, I don't have any details on that yet.
MR. RODAN: What?
MS. HALL: I don't have any details on who it is or -- standby. Speaker 3, Walter Tsou, please come up to the speakers' table.
MR. RODAN: Around the far side. Take care of the wire. I think you provided a copy at the front desk, we'll take it here. Watch out for the cord there, we don't want you falling over. Okay, so, we went through some long instructions. You have five minutes.
MR. TSOU: Okay. I'll be less. My name is Dr. Walter Tsou. I serve as Executive Director of Philadelphia Physicians for Social Responsibility and a past president of the American Public Health Association. Thank you for this opportunity to testify on "Strengthening Transparency in Regulatory Science". As many of my colleagues have noted today, while the goal of transparency in how studies are conducted, and the ability to

reproduce scientific results are important, it can offer a politically motivated administration a convenient excuse for eliminating or ignoring scientific studies that may go against the wishes of a powerful industry group. All one has to do is demand that the data sets be handed over for "further scrutiny" or demand that the study be repeated before basing a regulation on the study in question.

The very nature of longitudinal public health studies where health and toxins intersect are, by design, large, expensive and require years or sometimes decades before results are found. Sample sizes can often number in the tens of thousands to millions of data points and may need to be collected over many years before a statistically significant finding is identified. For example, Curry, et al studied in Pennsylvania babies who lived within 1 kilometer of active fracking wells. She had to review over 1.1 million birth records before demonstrating the relationship between living close to gas wells and low birth weight

babies. Because these studies are so big, they are often too expensive to repeat. In our state of Pennsylvania, scientific research on fracking is actively stymied or suppressed. In a state where billions are made on gas drilling, only one part time contractor at the Health Department collects data on health complaints from fracking. Those who do have health complaints have to sign non-disclosure agreements and not cooperate with any research in order to get lifesaving water to drink. This I consider extortion and this practice is common in the industry in order to suppress any health studies on the dangers of fracking. If the transparency regulation was in place, all health studies on fracking would be simply not considered because the research could not be conducted due to non-disclosure agreements.

Today there is no reputable scientist that doesn't believe in the harmful effects of smoking. The health studies on smoking were 15 years in the making before the Surgeon General released his landmark 1964 report and except for a handful of

EPA administrators, there is no reputable scientist who doesn't believe that climate change is real and is man-made. The studies on climate change and health have been known since Exxon wrote about it in 1977. If these transparency rules were in place when the EPA was founded, smoking would still be in airplanes and no one would have heard of "greenhouse gases" or "global warming", the greatest threat to our planet's existence.

Since the founding of the EPA, independent scientific research has been the foundational basis of your mission. Science is the cross before the corporate devil. This Transparency Rule would destroy the confidential nature of research and make the burden of conducting research more difficult and expensive. Finally, the real purpose of these rules is to reverse regulations on industries who have been harmful to public health. We should let science speak for itself and speak the truth and the EPA should hear from all scientific studies, not just the ones the industry

wants you to listen to. Thank you for your time.
MR. RODAN: Thank you very much. So, do we have any other registered speakers waiting? So we'll have a short recess and we have a one hour clock ticking. The time now is 4:22.
[Off the record 4:22 p.m.]
[On the record 4:40 p.m.]
MR. RODAN: We are hereby reconvening this public hearing. Come up to the -- go to the right there, there's some steps.
MS. HALL: Speaker Number 4, Mark Mitchell.
MR. BRUCE RODAN: Thank you, you'll have five minutes of time and you'll get a green light for the first four, an orange light and then a red light when the five minutes is up.
MR. MITCHELL: Okay, thank you. Thank you for this hearing. My name is Mark Mitchell. I'm a public health trained environmental health physician. I am testifying on behalf of the National Medical Association which represents the interests of more than 30,000 African-American physicians and our patients. We are a member

society of the Medical Society Consortium on Climate and Health.

I got into environmental health because I was concerned about the health effects of environment on public health. As a public health official, I saw that a lot of the diseases that are common, particularly those that are common in communities of color, are associated with the environment. We are opposed to the misnamed proposed new rule on "Strengthening Transparency in Regulatory Science." The proposed rule prohibits the Agency from setting regulations that are supported in part or in whole by data that is not publically available for reanalysis or that cannot be replicated. This rule, if enacted would limit the consideration of perfectly good science in the EPA regulatory process. What's more, it's retroactive so the current regulations that are based on previous studies that can no longer be replicated for ethical or other reasons, could then be voided. As physicians, we are particularly concerned about our legal and ethical obligation

to protect patient privacy under the Health Insurance Portability and Accountability Act of 1996, otherwise known as HIPAA. We believe that patient health data should be considered in EPA regulations because it's necessary to consider the health effects of environmental exposures in order to protect human health, and that we should also be able to guarantee patient privacy that should be protected.

Currently, we do this in research publications through the peer review process. The peer review process has worked well to ensure an adequate level of transparency while allowing science to advance unencumbered. We do not need to reduce the health protection that environmental regulations provide in the name of so-called "transparency." Thank you for this opportunity to testify.

MR. RODAN: Thank you. So, we'll go into another short recess, or maybe an hour, at 4:44. Thank you.

[Off the record 4:44 p.m.]

[Off the record 5:44 p.m.]

MR. RODAN: It's 5:44. I'll read the closing statement. Thank you for taking the time today to share your comments on the EPA proposed rule. The time is now 5:45 p.m. No additional members of the public have registered or are waiting to speak. Therefore, this hearing is now officially closed. Thank you.

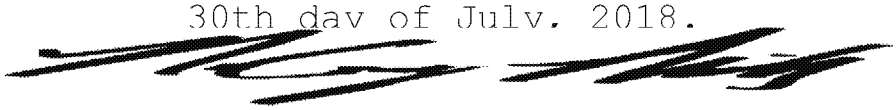
[Off the record 5:45 p.m.]

Whereupon, the above-entitled matter is concluded.

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, NaCorey Nichols, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.



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I, Gary Euell, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.

My commission expires:

March 14, 2023

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